

## **REMARKS**

Claims 32-61 are pending, with claims 32, 50 and 60 being the independent claims. Claims 32-50 and 60 have been amended. Claim 51 has been canceled. New claim 61 has been added. These amendments do not introduce new matter.

### **I. Specification**

By this Amendment, the specification has been amended in the paragraph beginning at page 18, line 15 and the paragraph beginning at page 19, line 8. These amendments do not introduce new matter.

### **II. Drawings**

Applicants have attached a "Replacement Sheet" including amended FIG. 7 for the Examiner's approval. In amended FIG. 7, reference element 200 has been renumbered as reference element 210. This amendment does not introduce new matter.

### **III. Objections**

The Examiner objects to the drawings because FIG. 6D includes reference element 228 which is not mentioned in the description. Applicants have amended the specification in the paragraph at page 19, line 8 by rewriting "a veinal leg 224" to "a veinal leg 228" to address the Examiner's objection.

The Examiner objects to the drawings because element 14 is allegedly used to designate both a "proximal single-lube extension tubes" and a "proximal veinal extension tube." Applicants respectfully disagree with the Examiner's objection. At lines p. 11, lines 15-17, it is disclosed that the catheter 10 includes a plurality of (i.e., two) proximal single-lumen extension tubes 14 and 16. Then at p. 11, lines 19-22, the proximal single-lumen extension tubes are more specifically identified as a proximal veinal extension tube 14 and a proximal arterial extension tube 16, respectively. Applicants submit that

reference number 14 clearly does not designate two different elements, rather the term “proximal single-lumen extension tube” is a genus, while the terms “proximal veinal extension tube” and “proximal arterial extension tube” are species of that genus.

The Examiner objects to the drawings because element 200 is used to designate both a square box 200 in FIG. 6D and a sheath dilator 200 in FIG. 7. Applicants have amended the paragraph beginning at page 18, line 15 of the specification such that each occurrence of “sheath dilator 200” is rewritten as “sheath dilator 210” to address the Examiner’s objection. FIG. 7 has also been correspondingly amended.

#### **IV. Claim Rejections - Double Patenting**

Claims 32-60 are rejected on the grounds of nonstatutory obviousness-type double patenting over claims 1-13 of U.S. Patent No. 7,300,430 and claims 1-11 of U.S. Patent Publication No. 2002/0099326.

Applicants submit herewith terminal disclaimers in compliance with 37 CFR 1.321(c) over commonly owned US Patent No. 7,300,430 and U.S. Patent Publication No. 2002/0099326 (Appln. Serial No. 09/769,052).

#### **V. Claim Rejections - Prior Art Grounds**

The Examiner rejects claims 32-60 under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,682,519 to Schon (“Schon”); and claims 32-60 under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,719,749 to Schweikert et al. (“Schweikert”). Applicants respectfully traverse these rejections in view of the following remarks.

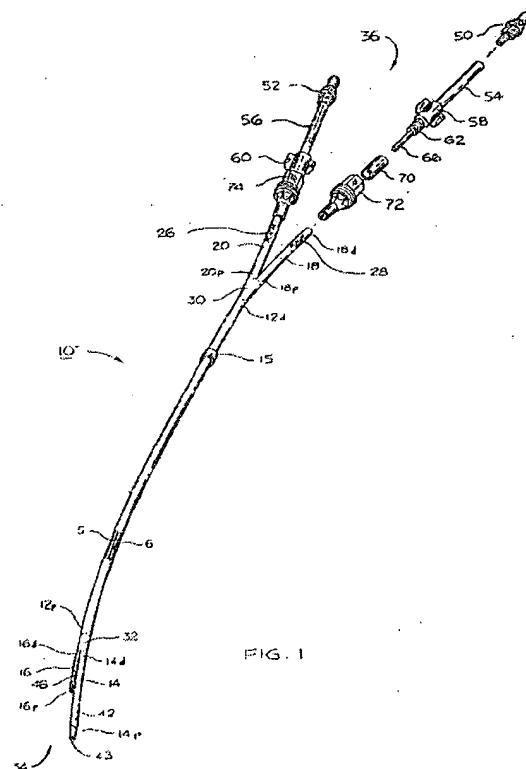
##### **A. Schweikert**

The Examiner relies upon Schweikert to teach each an every feature defined by claim 32. This rejection position is incorrect for at least the following reasons.

Independent claim 32 recites (among other things) “the proximal end of each distal single-lumen tube being permanently and directly connected to the distal end of

the multi-lumen tube portion.” At least this feature, in combination with the other features recited in independent claim 32, is not taught or suggested by Schweikert.

In the present application, a catheter 10 includes a multi-lumen tube portion 12 and distal extension tubes 18 and 20. The distal ends of each lumen 5 and 6 of the multi-lumen tube portion 12 are directly and permanently connected (e.g., sealably fused together by heat welding or the like) to the proximal ends of distal extension tubes 18 and 20, respectively. This connection between the multi-lumen tube portion 12 and the distal extension tubes 18 and 20 creates a smooth transition between the components, which facilitates the passing of the catheter 10 through a subcutaneous tunnel 102 during implantation of the catheter in a patient by a reverse tunneling procedure. Fig. 1 of the present application is reproduced below.



In contrast, Schweikert discloses a catheter 20 having first and second lumens 22 and 23 permanently connected to distal end tubes 26 and 30 by a hub 24. The hub 24 joins the catheter 20 to the distal end tubes 26 and 30. Fig. 1 of Schweikert is reproduced below.

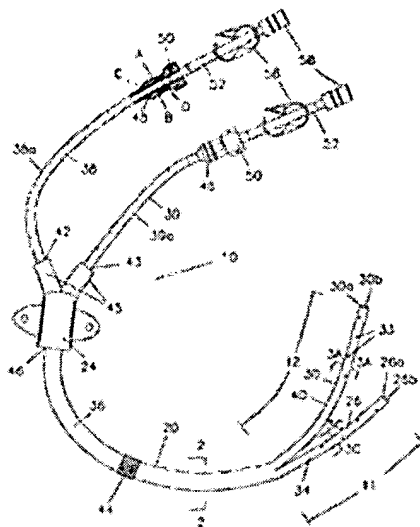


FIG. 1

A catheter assembly including a hub, as disclosed in Schweikert, cannot be inserted into a patient through the reverse tunneling technique described in the present application because the hub cannot be passed through a subcutaneous tunnel. Rather, the catheter must be inserted into a patient through forward tunneling process in which the hub remains outside of the body.

Therefore, Schweikert does not teach or suggest the “the proximal end of each distal single-lumen tube being permanently and directly connected to the distal end of the multi-lumen tube portion,” as required in independent claim 32.

Accordingly, Applicants respectfully submit that independent claim 32 is patentable over Schweikert, and kindly request that that the rejection be withdrawn as to independent claim 32.

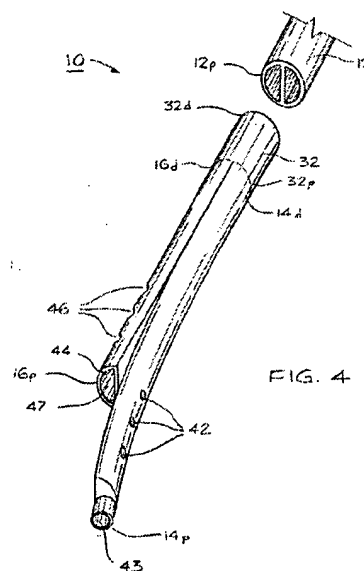
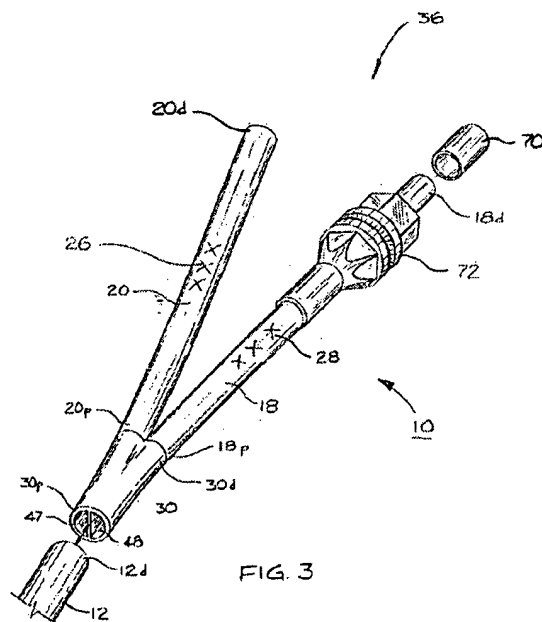
For reasons similar to those noted above with respect to independent claim 32, Applicants submit that independent claims 50 and 60 are patentable over Schweikert, and kindly request that the rejection be withdrawn as to independent claims 50 and 60.

## B. Schon

The Examiner relies upon Schon to teach each and every feature defined by claim 32. This rejection position is incorrect for at least the following reasons.

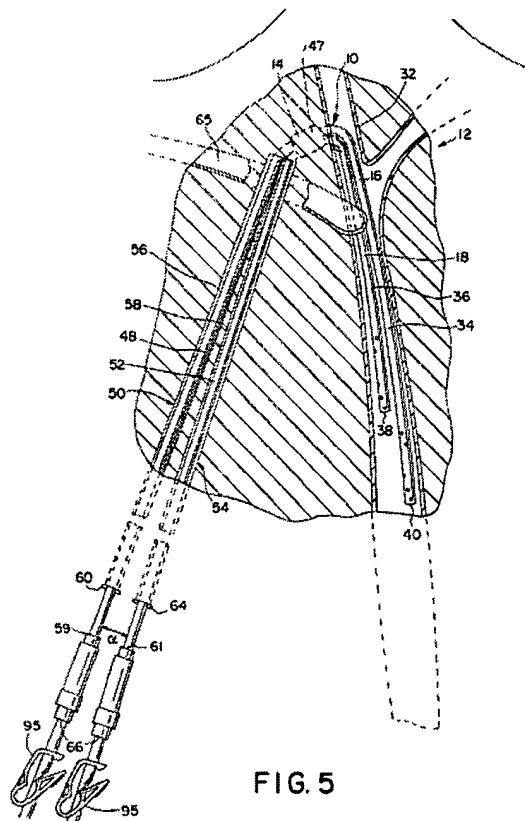
Independent claim 32 recites (among other things) a multi-lumen catheter having a "a one-piece multi-lumen tube portion having a plurality of integrally formed lumens." Further, independent claim 32 recites "a distal portion comprising a plurality of distal single-lumen tubes ... the proximal end of each distal single-lumen tube being permanently and directly connected to the distal end of the multi-lumen tube portion." At least these features, in combination with the other features recited in independent claim 32, are not taught or suggested by Schon.

As shown in Figs. 3 and 4 of the present application (reproduced below), the present application discloses a catheter 10 including multi-lumen portion 12 having two or more lumens 5 and 6. The two or more lumens 5 and 6 are formed within a single one-piece catheter tube.



In contrast, Schon (Fig. 5 reproduced below) discloses a multi-lumen catheter assembly 10 that is made from two separate catheters 16 and 18. The catheters 16 and 18 are unattached along their entire length or a portion of the catheters 16 and 18 are

bound together by a retaining sleeve 14. A catheter assembly including unattached catheters 16 and 18 certainly does not define a “one-piece multi-lumen tube portion having a plurality of integrally formed lumens,” and neither does a catheter assembly including catheters 16 and 18 bound by a retaining sleeve 14.



Further, in the present application, the distal ends of each lumen 5 and 6 of the multi-lumen tube portion 12 are “permanently and directly” connected to distal extension tubes 18 and 20, respectively. The only connection of any kind disclosed in Schon requires the use of connectors 66 to attach the catheters 16 and 18 to an external device. Therefore, Schon does not teach or suggest “permanently and directly” connecting the distal end of the multi-lumen tube portion to the proximal end of “distal single-lumen tubes.”

Accordingly, Applicants respectfully submit that independent claim 32 is patentable over Schon, and kindly request that that the rejection be withdrawn as to independent claim 32.

For reasons similar to those noted above with respect to independent claim 32, Applicants submit that independent claims 50 and 60 are patentable over Schon, and kindly request that the rejection be withdrawn as to independent claims 50 and 60.

**CONCLUSION**

In view of the preceding amendments and remarks, reconsideration and withdrawal of the various objections and rejections set forth in the Office Action is respectfully requested.


Pursuant to 37 C.F.R. §§ 1.17 and 1.136(a), Applicants hereby petition for a three (3) month extension of time for filing a reply to this Office Action.

A check for \$1,390 is enclosed to cover the \$1,110 fee for the three (3) month extension of time for a large entity and the \$280 fee to cover the two (2) terminal disclaimers.

If any additional fee is required to maintain the pendency of the subject application, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 01-1785.

Respectfully submitted,  
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